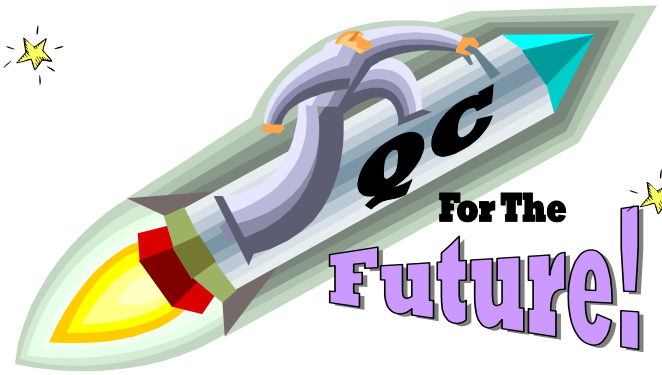


CLINICAL AND LABORATORY STANDARDS INSTITUTE

(Formerly NCCLS)
Providing NCCLS standards and guidelines,
ISO/TC 212 standards, and ISO/TC 76 standards

# Agenda
# Baltimore, Maryland
# March 18, 2005

**Moderator: Robert Habig, Ph.D., V.P. Regulatory Affairs, Abbott Laboratories**

| Time | Topic | Speaker |
|---|---|---|
| 8:00 | **Introductions and Goals for the Meeting**<br>Overview of goals, approach, agenda, and NCCLS' role in QC consensus document development. Importance of collaboration between government, laboratories, and manufacturers to ensure test quality. | **Thomas Hearn, Ph.D.,**<br>President, NCCLS<br>Director, Division of Laboratory Systems, CDC |
| 8:15 | **History of QC**<br>Background and historical perspective of QC. | **Joseph Boone, Ph.D.,**<br>Associate Director of Science,<br>Division of Laboratory Systems, CDC |
| 8:35 | **CLIA QC – Options for the Future**<br>Current CLIA QC regulatory requirements including EQC options. Potential for non-regulatory alternatives or professional standards under the current regulation. Role of government in development, oversight and enforcement of laboratory QC standards. | **Judy Yost, MA,**<br>Director, Division of Laboratory Services, CMS |
| 8:55 | **Technology Variations**<br>Different technologies require different mechanisms for QC. Current and future technologies and their innovative concepts for QC. Role of manufacturer in QC and test quality. | **Fred Lasky, Ph.D.,**<br>Director, Regulatory Affairs<br>Genzyme Diagnostics |
| 9:15 | **Laboratory Issues – POCT/POL Concerns**<br>Quality issues and concepts in the less sophisticated vs the large central laboratory. Role of the laboratory in QC and test quality. | **Valerie Ng, M.D., Ph.D.,**<br>Professor and Interim Chair,<br>Department of Laboratory Medicine<br>UCSF |
| 9:35 | **Break** | |
| 9:55 | **What is Laboratory Quality Today?**<br>Discussion of what constitutes quality in a laboratory from one of the world's premier QC experts. | **James Westgard, Ph.D., FACB,**<br>President, Westgard QC, Inc |
| 10:15 | **Personnel Issues**<br>Role of personnel in QC and test quality - the quality of the test result is directly related to the personnel performing the test.<br>Current status of testing personnel shortage, training and personnel competency protocols. | **Elissa Passiment, Ed.M., CLS(NCA)**<br>Executive V.P., ASCLS |
| 10:35 | **Risk Management**<br>Introduction to ISO and US manufacturing concepts of risk management. Mitigate test system errors and improve test system accuracy. How risk management can interface with QC practices. | **Donald Powers, Ph.D.,**<br>President, Powers Consulting |

# QC for the Future!
## Agenda
## Baltimore, Maryland
March 18, 2005

| Time | Topic | Speaker |
|---|---|---|
| 10:55 | **NCCLS Standard Development**<br>Timeframes, players and process for NCCLS consensus standard development. Proposed concept for draft NCCLS standard for QC | **Luann Ochs, MS,**<br>Director, Regulatory Submissions<br>Roche Diagnostic Corporation |
| 11:15 | **Panel Discussion**<br>Collaboration of manufacturers, government and laboratory professionals in the development of QC practices and policies.<br>Each constituency's role in ensuring test quality.<br>Issues/concerns identified during presentations and plans to address them ongoing. What should QC monitor? | **All Speakers** |
| 11:45 | **LUNCH (INCLUDED)** | |
| 1:00 | **Breakout into Workgroups** | |
| | • **Consensus Standards/Option 4 Proposal**<br>Subject experts to provide initial input into proposed NCCLS document that could constitute Option 4 for CLIA QC compliance. Document to be completed at a later date. | **Luann Ochs** |
| | • **Future Technology from Lab Perspective**<br>Experts to provide data, experiential information to be considered in possible additional EQC options or adjustments to current options. Discuss the advantages and limitations to technology. Discuss the relationship of personnel competency to technology and QC. Develop a plan for QC for the future. | **Valerie Ng** |
| | • **Input into Regulations/Guidelines**<br>Discuss pros and cons of regulatory requirements vs professional standards vs interpretive guidelines. Ensure standards reflect current state of technology and balance with ensuring quality. Experts submit ideas and data for alternative options for EQC and help outline short and long-term QC plans for the future. | **Judy Yost** |
| 4:10 | **Reports from Workgroups**<br>Each workgroup will summarize outcomes and issues from their group to be placed in the QC plan for the future. | **Robert Habig** |
| 4:40 | **Summarize Future Plans**<br>Summary of the findings and outline of QC plan for the future. Next steps needed to complete work begun at this session, anticipated timeframes, and responsible party. | **Thomas Hearn** |
| 5:00 | **Q & A Session** | **All** |
| 5:25 | **Wrap Up/Adjourn**<br>Thank all participants and invite continued participation. | **Thomas Hearn** |